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Ethical Issues Related to Patenting of Animals

June 1988

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ETHICAL ISSUES RELATED TO THE PATENTING OF ANIMALS

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June 8, 1988

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Part I - Introduction

On April 7, 1987, Donald J. Quigg, Commissioner of Patents and Trademarks, announced that:

> The Patent and Trademark Office now considers non-naturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 USC 101 [4, p. 22].

Slightly more than one year later, on April 13, 1988, patent #4,736,866 was issued to Harvard University. It covers a new breed of genetically altered mice which can serve as a more effective model for studying how genes contribute to the development of cancer and for testing new anti-cancer drugs because the genetic altering results in half the females of the breed developing cancer [21].

In response to the earlier announcement, a number of bills were introduced. One (H.R 3119, introduced on August 5, 1987, by Congressman Rose and others) mandated a two-year moratorium on patenting new animals while Congress studies the issues. It explicitly argued that the decision to allow such patents raises such fundamental economic, environmental, and ethical questions that it should be made by Congress and not by the Patent and Trademark Office. Another (S. 2111, introduced on February 29, 1988, by Senator Hatfield) simply banned such patents, presumably because its author judged that these questions clearly indicated that patenting is inappropriate. A series of hearings were held in the second half of 1987, but no bill actually passed both houses of Congress and became law.

This is the context in which this report is prepared. It will in no way address the procedural question as to whether the decision by Commissioner Quigg should have been left to Congress; this report

focuses only on the substantive question of the merits of allowing patents on new breeds of multi-cellular animals produced through genetic engineering (hereafter referred to as transgenic animals). Moreover, this report will be confined to examining only those arguments for and against such patents which have a philosophical, moral or religious component. Its goal is to provide to those who are considering the substantive issues a comprehensive presentation of these arguments and a critical and balanced evaluation of them.

No attempt will be made to evaluate these arguments in terms of a single overarching moral or religious viewpoint. Such an attempt would be of use only to those who accept that particular viewpoint. Moreover, many viewpoints are too abstract to really help in the understanding and evaluation of the actual arguments which have been offered. Instead, this report is organized around an evaluation of the arguments with a philosophical, ethical, or religious component actually offered by one or more of the parties who have spoken out publicly on this issue, using in the evaluation criteria which are likely to be acceptable to the broadest possible community of citizens. When dealing with arguments which presuppose a special moral or religious viewpoint, we will attempt to specify the viewpoint in question and indicate the broader implications of adopting such a viewpoint.

Part II - Arguments for Patenting Transgenic Animals

Section A - Patenting Transgenic Animals Promotes Useful Scientific and Technological Developments

The basic purpose of the patent laws is found in the section of the Constitution which authorizes the creation of

such a system. Congress is given the power:

> To Promote the Progress of Science and the Useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries [U.S. Constitution, Article 1, Section 8].

The presupposed argument is straightforward: granting patents increases the incentives for inventors to develop useful inventions, so a well-organized society should have such a system of patents. Some would see this argument as a purely pragmatic one, appealing to considerations of social policy and lacking any moral component. This would be an error. Defending social institutions on the social policy grounds that they lead to desirable consequences (such as encouraging inventions) is a form of moral reasoning, usually called consequentialist reasoning, that has great moral significance, even if most would agree that it is only one of many moral arguments which need to be considered in any particular case.

There is no doubt that this is the basis of the most widely used argument by proponents of patenting transgenic animals. Thus, in testifying before Congress on June 11, 1987, Assistant Commissioner for Patents, Rene Tegtmeyer, asserted:

> By granting the right to exclude others, the law provides an incentive for those who create and develop new technology... The grant of patent rights has in fact encouraged research and provided useful new products including research into solutions of problems such as those associated with genetic disorders and increasing food yields [4, p. 21].

Similar claims were advanced by many others who testified on behalf of the biotechnology industry [ibid., pp. 140-9] on behalf of some segments of the agricultural community [ibid., pp. 118-121], or on behalf of communities of research scientists [ibid., pp. 211-4].

By their very nature, consequentialist arguments provide greater or lesser support for a social policy depending upon the probability of the outcome (the higher the probability, the stronger the support) and upon the desirability of the outcome (the more desirable the outcome, the stronger the support). This fundamental feature of consequentialist arguments makes their support difficult to assess in particular cases, for it is often hard to tell how desirable will the outcomes be and how likely are they to occur. This holds in our case as well. How much benefit will accrue from the development of new animal breeds by a biotechnology encouraged by patents? How likely is it that these benefits will actually be produced? These are not easy questions to answer. What can be said, however, is that the tremendous growth of the biotechnology industry, both nationally and internationally [18], based upon the tremendous growth of the scientific community's efforts in this area, suggests that a large number of knowledgeable observers are prepared to invest their time and energy and/or their money on the assumption that biotechnology, in general, and the development of transgenic animals, in particular, holds out tremendous possibilities for useful - and marketable - advances. Given that fact, and given America's general experience with the ways in which patents do encourage inventions, it seems reasonable to conclude that there is substantial consequentialist support for the patenting of transgenic animals.

There is, however, another feature of consequentialist arguments that must be considered. In assessing the support such arguments offer for a social policy, we must consider negative as well as positive consequences. Opponents of the patenting of transgenic animals are well aware of this fundamental feature of consequentialist arguments, and they offer a variety of suggestions about the negative consequences of the patenting of new breeds of animals. We will be considering them below in part III of this report. For now, let us simply say that we should draw no conclusions about the consequentialist merits of patenting transgenic animals until those arguments are identified and evaluated.

We should also note that some who have argued for patenting have not taken this feature of consequentialist arguments into account. Consider, for example, the argument offered by Robert P. Merges, from Columbia University School of Law, in his testimony before Congress on July 20, 1987:

> The arguments against animal patents are arguments about <u>consequences</u>: animal suffering, hardship for the small farmer, and reduction in genetic diversity. This is rare: arguments about patentability seldom turn on the social effects or implications of the subject matter [4, p. 18].

Whether rare or not, considerations of consequences seem perfectly relevant. If we are to allow for the patenting of transgenic animals on grounds other than the fact that such patents fall under the statutory language, language which could easily be changed, we will have to do so on grounds of the social benefits that will be produced by allowing such patents. A consideration of the logic of such

consequentialist arguments demands that we consider possible harms as well.

We conclude this section then with the judgment that there are substantial consequentialist arguments for allowing the patenting of transgenic animals, but that their ultimate significance will depend upon the assessment of the possible harms which will be presented in Part III of this report. Only when both harms and benefits have been identified can their relative strengths be addressed.

Section B - Patenting Transgenic Animals is Necessary for America to Compete in an International Marketplace

Those who argue for the patenting of transgenic animals on consequentialist grounds usually refer to such direct beneficial consequences as improving the food supply, providing animal models for the study of human diseases, and providing a means to efficiently produce pharmaceuticals. In addition, they often refer to the fact that allowing such patenting is necessary if America's biotechnology industry is to be able to compete internationally. To quote William H. Duffey of Monsanto Corporation in his testimony of July 22, 1987:

> America's competitiveness is the centerpiece for international trade discussions today. Intellectual property is a prominent component of that centerpiece. America's competitiveness can be strengthened by providing more effective legal protection for American technology. Congress would be going in the wrong direction to consider limiting protection for biotech inventions... [ibid., p. 146].

Again, those who would see this argument as a purely pragmatic argument, appealing to social policy considerations and lacking any moral component, would be in error. A society which wishes to find employment for its citizens, to fund needed social programs such as support for the indigent, and to support education and learning needs to adopt measures for promoting economic growth in an increasingly competitive international marketplace. If the patenting of transgenic animals would make a significant contribution to promoting such growth, that would provide us with an additional set of consequentialist reasons for supporting the patenting of such animals.

There is, however, a fundamental difficulty with this argument. Although the precise legal situation governing the patenting of animals throughout the world is unclear - and we will return to that unclarity below in Part III - it can surely be said that many of the countries with which we compete do not allow and would not recognize patents on transgenic animals. Given that that is so, it is difficult to see how America's biotechnology industry is hampered by not being able to obtain the patents that others also cannot obtain, and it is unclear that it would be helped in an international marketplace by obtaining patents that so many other countries would not honor. The whole legal situation may, of course, change, and that will effect the merits of this particular consequentialist argument; as things currently stand, the argument from international competitiveness is not particularly strong.

Section C - A System of Patenting is Preferable to a System of Trade Secrets

There is still a final consequentialist argument which needs to be considered. It relies upon the fact that patents are not the only way to protect intellectual property rights. One alternative would be to treat biotechnology developments as trade secrets. If patents were not issued on transgenic animals, then those who developed such animals would attempt to protect their commercial value by treating them as trade secrets. The final consequentialist argument to be considered suggests that this would have very unfortunate consequences for society.

Why? This is due to a crucial provision in the patent law. In order to obtain a patent, one normally submits a complete specification, which is a description which would enable one skilled in the relevant art to make and use the invention. Alternatively, one can deposit the invention (if, for example, it is a microorganism) in depositories which will provide cultures to requestors after the patent is issued. Whichever approach to the so-called enablement requirement is adopted, a system of patenting provides a great deal of new information which is used by scientists and by competing companies to develop (without infringing upon patent rights) alternatives to and improvements on the patented invention. If companies resorted to trade secret protection of intellectual property rights in transgenic animals, primarily because patent protection was not available, then this sharing of information would be limited. In this way, patenting contributes to the growth of knowledge. To quote Ann Sorensen of the American Farm Bureau Federation in her testimony of July 22, 1987:

> Science works in a building block fashion - one discovery building on another - and scientists must have access to the discoveries. For this reason, patents, even with the delays involved in publishing, are probably preferable to trade secret protection [ibid., p. 123].

A very nice example of this was provided by William Duffey in his testimony:

> Cortisone was the leading patented discovery in the steroid field. Cortisone was promptly followed by a host of non-infringing competitive inventions by others, each of which inventions was stimulated by the initial disclosure by the cortisone inventor... The patent history book is replete with examples like the cortisone steroid technology [ibid., p. 141].

It should be noted parenthetically that this argument for the patenting of transgenic animals gives rise to an important technical problem raised by Senator DeConcini in a letter of 2 August 1987 to Commissioner Quigg. If this advantage of patenting is to be realized, asked Senator DeConcini, would there be a need for legislation to insure that patented animals used for legitimate research purposes would be covered by the experimental use doctrine so that the researchers would not be engaging in impermissible infringement on the patent rights? It is beyond the scope of this report to examine this issue more fully, but it should at least be noted at this point.

How successful is this additional consequentialist argument? Our previous remarks about the difficulty of assessing the support of consequentialist arguments for a given social policy apply here as

well. However, it once more seems reasonable to judge that, particularly in a field where scientific advances are proceeding rapidly, patents would be more helpful for scientific progress than trade secrets, and that this is an additional argument for allowing patenting. Again, however, it is important to remember that we will need to weigh this additional benefit of patenting against any possible harms which it would produce, harms which we will examine in Part III, before we come to any conclusions.

Section D - Patenting Transgenic Animals Provides an Appropriate Reward for Innovation and Entrepreneurship

All of the arguments presented until now have been consequentialist arguments. Still a final argument for patenting, an argument of a non-consequentialist nature, is suggested in the following very important remark made by Leroy Walters of the Kennedy Center for Bioethics in his testimony of November 5, 1987:

> The moral justification for legal practices like patenting and copyright have received scant attention in the literature of ethics. The general rationale for both the copyright and patent systems is that they encourage the investment of time and energy in the act of creating... Unless and until these revered systems produce serious harm to human or animal welfare, they should be preserved intact as an ethically appropriate way of acknowledging the initiative and creativity of authors and inventors [ibid., p. 389].

There are actually two very different moral justifications for patenting contained in Dr. Walters's remarks. The first, that the

system of patents encourages inventions, has been discussed above; it is the fundamental consequentialist argument discussed in Section IIA. The second, suggested at the very end of his remarks, is a very different argument, the argument that inventors are entitled to patents as an acknowledgment of their efforts. This important argument deserves further elaboration.

There are several different moral bases for any system of property rights, and each of them can be applied to intellectual property rights as well. In an important recent discussion [11] Alan Goldman has divided them into forward looking arguments (the appeals to consequences which we discussed above) and backward looking arguments. The latter justify property rights as entitlements to the fruits of our labor, drawing upon themes deriving from John Locke's seminal discussion of property rights [15]. Applied to the area of patenting transgenic animals which result from biotechological research, this argument concludes that inventors are entitled to patent rights as a way of giving them the fruits of their labor when their labor is more intellectual than physical.

Several points should be noted about this argument: (1) it introduces into patent law a moral theme not normally present in that area of the law. Nevertheless, it may well be a legitimate theme to introduce. It certainly seems to capture some of what those who are working in the field say about their rights to a patent; (2) there are many fundamental intellectual challenges to such a theory of property rights, even though recent studies [1] have suggested that they can be met. This moral argument for intellectual property rights awaits further development before it can be used as a secure basis for public policy. Among the issues which need further analysis are: (a)

whether this argument is best formulated as an appeal to merit or to entitlements; (b) what is the extent of the intellectual property rights which such an argument would justify; (c) what are the constraints on the exercise of such property rights; (3) Goldman calls attention to the fact that such entitlements may make less sense in the context of corporate and university research (especially federally funded university research) than in the area of individual research. Moreover, in any area, they need to be balanced against considerations of public need to the fruits of research. Perhaps, however, that balancing is already accomplished by the satisfaction of the enablement requirement which enables others to use the information to develop other ways of meeting public needs which do not infringe upon the patent.

What conclusion can be drawn then about this backward-looking moral argument for intellectual property rights? Perhaps the most that can be said at this point is that it is suggestive of an alternative approach to the justification of patent rights in transgenic animals, an approach which ought to be carefully analyzed by future scholars to determine its usefulness for policy debates.

Section E - Summary of Part II

There are then significant arguments for patenting transgenic animals. It is reasonable to expect that such a system of patents will encourage the development of useful inventions and will make available information which will be used as the foundation of further scientific investigations. Moreover, if patent law changes in other countries, such a system will be needed to protect American competitiveness in an international marketplace. All of these factors

provide us with consequentialist defenses of such a system of patent rights. These consequentialist considerations may be reinforcable by an appeal to patents as a way of satisfying the inventor's entitlements to the fruit of his or her labor.

This case, while impressive, is not conclusive. It remains to see whether there are consequentialist arguments against patenting transgenic animals based upon possible bad consequences of such a system. It also remains to be seen whether there are still other types of moral considerations which speak against patenting. We will examine these issues in the next part of this report.

Part III - Arguments Against Patenting Transgenic Animals

Section A - Metaphysical and Theological Arguments Opposing the Patenting of Transgenic Animals

The most fundamental arguments opposing patenting draw upon metaphysical and theological claims rather than upon moral claims. They raise questions about the relation between the living and the non-living and about the relation between human beings and the world which they inhabit. Moral conclusions are drawn at the end of these arguments, but they begin with non-moral philosophical and the ological claims.

There is one feature of these arguments which needs to be noted. The proponents themselves recognize that they need to do a lot more work to articulate the inchoate concerns they feel. This is why the recent statement of the religious leaders against animal patenting called for a moratorium on patenting while a process of "thoughtful reflection and judgment on these matters by churches and religious

institutions, as well as by other concerned groups in our society" is carried out [25]. All that we can do in this section is to examine the articulations of concern that have already been developed. We need to be sensitive, however, to the possibility that further articulations of reasons for opposing patenting may be forthcoming.

Shortly after the Chakrabarty decision in which the Supreme Court ruled that a living microorganism was patentable, Leon Kass published an important essay in which he raised a number of fundamental questions about the patenting of living organisms of any size or complexity. Here, we focus on one argument which he stated as follows:

> Consider first the implicit teaching of our wise men, that a living organism is no more than a composition of matter, no different from the latest perfume or insecticide. What about other living organisms - goldfish, bald eagles, horses? What about human beings? Just compositions of matter? Here are deep philosophical questions to which the Court has given little thought, but in its eagerness to serve innovation, it has, perhaps unwittingly, become the teacher of philosophical materialism [14, pp. 149-50].

Reinforcing Kass's point was the fact that the majority in Chakrabarty was required to find that the organism was a composition of matter, because the statute authorizing patents refers to "...any new and useful process, machine, manufacture, or composition of matter" as patentable objects, and the relevant microorganism only fell under the last phrase. This aspect of the decision was also the basis of criticism of it by a working party of the World Council of Churches:

> The U.S. Supreme Court decision on patenting of life forms rested upon a specific, highly reductive conception of life, which sought to remove any distinction between living and non-living matter that could serve as an obstacle to the patenting of living but unnatural organisms [26, p. 47].

This report is obviously not the place to examine the great philosophical debate between materialists, who see living objects as nothing more than complexly organized matter, and non-materialists, who insist that living objects are more than that. Let us leave that question unresolved. Let us go further and agree with Kass that it would be inappropriate for society to adopt a social policy which committed us as a society to a materialistic conception of life. Still, there is nothing in the decision to patent living things - even under the current language of the patenting statute - which commits us to a materialistic conception of life. Even those who believe that living beings are more than compositions of matter believe that they are at least compositions of matter, and it is only as compositions of matter that we patent them. No doubt, if the genetic altering which is being patented produces results which are harmful to these living entities, then that does raise moral issues, for living entities (or at least some of them) can be harmed - their interests can suffer - while the non-living cannot. These moral issues of possible harm will be raised in future sections, however, and we will see there whether they only require adequate regulations or whether they require a ban on the technology or on patenting its results.

A second argument, that some of the genetic engineering being patented confuses what must be kept distinct, is found in a passage in

the recent statement of religious leaders against animal patenting. They make the following claim:

> The combining of human genetic traits with animals, with the results to be patented and owned, raises unique moral, ethical, and theological questions, such as the sanctity of human worth, which must be examined [25].

A good example of what they have in mind is, of course, the introduction of genes for the human growth hormone into farm animals to produce greater growth.

The sanctity of human worth is, of course, a fundamental moral principle of our society, standing behind our belief that humans cannot be killed or mistreated, are entitled to freedom from enslavement, and so forth. Since we allow animals to be killed for food and to be owned, we do not subscribe to a similar sanctity of animal worth principle. After all, a sanctity of worth principle would seem to imply at least the following two elements: (a) the life of the entity in question is of sufficient value that it can be taken only in the most extreme circumstances (e.g., self-defense); (b) the individual is free to act as it desires, for it should not be treated as a mere means for others to attain their ends. By killing animals for use as food, we show that we do not ascribe such significance to their lives. By allowing them to be owned by those who would raise them for use as food, as a source of various by-products (e.g., wool), as objects to be entered into competitions, or even as pets, we show that we are willing to treat animals as mere means to human ends. All of this is, of course, perfectly compatible with insisting that unnecessary animal suffering should be eliminated. So our moral life, as currently

constituted, rests upon the distinction between humans and animals. It would seem, then, that the religious leaders see such genetic experiments as imperiling the belief in the sanctity of human worth by breaking down the barrier between humans and other animals.

Do they? If it were possible (and it is not possible either now or in the foreseeable future) to genetically alter animals so that they had more of those capacities and features (e.g., the capacity to form moral judgments or the capacity to experience the beautiful and the sublime) which we see as distinctive to humans, then we would face difficult moral questions as to how such creatures should be treated and as to whether we can continue to maintain a sharp divide between humans and other animals. But, of course, none of these issues is raised by farm animals who grow more because they have a gene which leads them to produce human growth hormone. Nor would they be raised by any of the genetic alterations of animals which will be produced in the foreseeable future. So in what ways do these experiments raise questions about the sanctity of human worth? And in what way does the patenting of their results imperil that belief?

We turn finally to an interconnected series of arguments about man's control over nature, man's responsibility toward nature, and the need to preserve species and protect their integrity which are probably the leading cause of metaphysical and theological disquiet about the patenting of transgenic animals and about the genetic engineering it will promote. A powerful statement of this set of issues is contained in the following testimony of the Rev. Wesley Granberg-Michaelson, appearing on behalf of the National Council of Churches, on November 5, 1987:

> When the National Council of Churches has issued this statement of concern, it comes from the background of Judeo-Christian thinking about how we relate to the natural environment. In a nutshell that background says that we have a responsibility for preserving the integrity of the creation, and for working with it in order to preserve its intrinsic values... the doctrine of trust in legal parlance is synonymous to what we are talking about theologically or religiously when we think about the relationship of the creation to humanity. The Judeo-Christian view says that the creation is, in essence, held in trust; there are limitations on what we can do. We have a responsibility to see that its integrity is preserved. This background has led to legislation such as endangered species laws, animal welfare laws, laws regarding environmental quality [4, p. 394].

There are those who might be tempted to reinforce these theological considerations by appealing to the metaphysical notion of the telos (nature) of animals which has been used by the philosopher Bernard Rollin in his recent work on animal rights [23]. They might claim that animals have a right to have their telos respected, and that patenting of transgenic animals is immoral because it is sanctioning an immoral violation of this right to an inviolable telos. Rollin [24] has made it clear, however, that he does not subscribe to this interpretation of his work. For him, we need to take an animal's telos into account to insure that changes do not inappropriately harm

the animal; there is no moral objection, however, to changing its telos.

Let us return then to Granberg-Michaelson's presentation of the theological argument. There are several points which I want to make: (1) the presentation of the Judeo-Christian tradition is somewhat misleading. As John Passmore showed in his groundbreaking study, Man's Responsibility for Nature [20], the traditional Judeo-Christian image was that of man's dominion over nature. To give but one example, Calvin repeatedly talked about the fact that God created all things for man's sake. It is only in recent years that the theme of man's stewardship over nature has become more predominant; (2) the traditional idea of a steward or of a trustee is the idea of a person who manages property for the benefit of other persons (present and future) who are its owner. There is nothing in the traditional conception of stewardship or trusteeship which even suggests that the property is to be managed to preserve its integrity for its own sake. Property held in trust can be radically transformed by trustees if it serves the best interest of its human owners, present and future. One religious notion of stewardship - the only one that is required to defend environmental protection statutes and perhaps endangered species laws [16] - is the notion that man must treat the property he owns as a trust for those human beings who will follow in future generations and cannot over-exploit it so as to maximize his current benefit. This notion of stewardship is analogous to the legal notion of trusteeship, but it is not the notion which Granberg-Michaelson is employing. He is using the different notion of the steward who protects the integrity of the property for the property's sake; (3) this radically new notion may be morally desirable, but its claims

demand considerable justification, and only those who are prepared to accept its many radical implications are entitled to use it as the basis for arguing against transgenic animals and the patenting of them. This argument is analogous to some of the arguments used by some animal rights advocates, arguments which we will examine in the next section, in that it is based upon a radical revision in our metaphysical conception of the relation of human beings to non-human nature.

Section B - The Patenting of Transgenic Animals Involves Inappropriate Treatment of Animals

In the current debate surrounding the patenting of transgenic animals, the animal rights movement has taken a leadership role in opposing such patenting. Particularly prominent has been the opposition of the Humane Society of the United States. Its president, John Hoyt, presented a number of major arguments in his testimony before Congress. For our purposes, we will focus on three of his arguments:

(1) The development of transgenic animals, encouraged by patenting, will lead to far more animal suffering than changes produced through selective breeding and cross breeding:

> Genetic engineering is of a wholly different order of magnitude, in that in traditional breeding practices, genes cannot be exchanged between unrelated species. Furthermore, genetic changes can be wrought very rapidly through genetic engineering... If the patenting of animals is permitted, there will surely be a dramatic increase in the suffering of animals... This for the reason that the outcome of many genetic

> experiments cannot be predicted in relation to the animals' health and welfare... [4, pp. 62-3].

An example often used by Michael Fox, the Society's Scientific Director, is the health problems (arthritis, lethargy, defective vision) of the USDA's transgenic pigs carrying the human growth gene.

(2) Patenting reflects an inappropriate sense of human control over animal life and an underestimation of the value of non-human life:

> From an ethical perspective, the patenting of animals reflects a human arrogance towards other living creatures that is contrary to the concept of the inherent sanctity of every unique being and the recognition of the ecological and spiritual interconnectedness of all life [ibid., pp. 64-5].

(3) The patenting of animal life is the first step towards a decline in the belief in the sanctity and dignity of life:

> To permit the patenting of just one animal will effectively eliminate all constraints... against genetically altering all other animals including human beings [ibid., p. 65]

There is a crucial difference between these three arguments. The first appeals only to the moral claim that animal suffering is wrong and should be avoided, a claim which is consonant with most moral views about animals. The second and third go beyond that and depend upon far more controversial claims which we will identify below. This difference will be essential to our analysis of the arguments.

Let us first examine argument (1). The history of western moral thought shows a tremendous diversity in attitudes towards animal

suffering [19, Chapter 4]. Cartesians have been least sympathetic to any concern about such suffering. Aquinas and Kant saw the moral significance of humaneness towards animals as due to the way in which it encourages humans not to be cruel to each other. It is only in the Benthamite tradition that animal suffering and human suffering began to be seen as morally similar to each other, although even contemporary Benthamites such as Peter Singer allow for some significant differences in degree. Finally, contemporary thinkers such as Tom Regan have advanced the idea that animals have a presumptive right not to be harmed. Obviously, this report is not the place to attempt to resolve this dispute. How then shall we assess argument (1)? I suggest the following: recent federal legislation (including the Animal Welfare Act of 1985) and regulations (including the 1985 PHS policy) covering animal research clearly indicate that our society now accepts the idea that animal suffering has moral significance and should be avoided. The fact that it mandates costly improvements in animal care clearly indicates that our society also accepts the idea that human interests do not always outweigh animal interests. The fact that the conducting of the research is not regulated - except for the rules covering anesthetizing animals - clearly indicates that we still see human interests as taking precedence over animal interests. All of that being the case, we should, I suggest, evaluate argument (1) in light of the current socially adopted attitudes towards animal suffering, keeping in mind that those who ascribe even greater moral significance to animal suffering will be even more troubled by argument (1).

Spokespeople for the biotechnology industry have suggested [13] that the genetic engineering of farm animals may actually minimize

animal suffering by engineering disease - resistant traits into farm animals. A good example of this would be the attempt to engineer chickens to be resistant to the avian leukosis virus. But that doesn't meet argument (1), for we are hardly in a position to be sure that the gains to animals will outweigh the losses. It is relevant to remember that the first patent is for mice engineered to develop more cancer, and no provisions have been made to insure that these animals will be killed as soon as possible to avoid their suffering the full effects of their cancer's producing their death.

It might be suggested that the current regulatory mechanisms will protect animals against unnecessary harm in the research which patenting will encourage. This seems not true. The Animal Welfare Act does not apply to rodents, birds, and farm animals intended for use as food or livestock [19, Chapter 13]. The PHS regulations apply only to federally funded research [ibid.]. It appears then that there are no regulations in place to protect many animals used in research in industrial laboratories.

Leroy Walters has pointed out that:

> The ethical issues related to interspecies gene transfers or the patenting of animals will probably be clarified if they are distinguished analytically from the animal-welfare question... Further, the goal of securing more humane treatment can be, and is being, approached directly through such means as legislation and regulations... [4, p. 388].

This point is correct. Argument (1) really cannot show that the encouragement of the development of transgenic animals by patenting is wrong because it will lead to inappropriate animal suffering.

Regulations appropriately governing such research are an alternative way of dealing with that problem. We can have the benefits of biotechnology while protecting animals from inappropriate suffering. But we need to remember that a failure to strengthen the regulatory scheme to protect against unnecessary suffering of farm animals, birds, and rodents in industrial research will pose a moral problem for the whole system of research encouraged by the issuing of patents. That, I believe, is the appropriate conclusion to be drawn by those who are committed to the understanding of the moral significance of animal suffering embodied in current legislation and regulation. Naturally, the greater the moral significance one ascribes to animal suffering, the stronger the regulations one will require to meet this problem.

Arguments (2) and (3) are very different, as we have suggested above. They appeal to stronger moral claims than the claim that animal suffering should be avoided. But it is unclear as to what claims are being presupposed. Argument (2) talks about "the inherent sanctity of every unique being." Those who talk about the sanctity of something are usually ascribing great value to its continued existence and flourishing. As pointed out in the last section, it is hard to see how a society which is willing to slaughter animals for food can be viewed as committed to a belief in the inherent sanctity of every unique being. So argument (2) is appealing to premises about animals not acceptable by most, and should be advocated only by those who are prepared to accept all of its radical implications.

A similar type of premise must be presupposed by those who advocate argument (3). Why can we not differentiate between patenting genetically altered animals and patenting genetically altered humans? Most people would, I submit, have no difficulty doing so, and one need

not lead to the other. One will lead to the other only if we treat the distinction between animals and humans as insignificant, and that claim of the insignificance of the human/animal distinction must be the presupposition of those who offer argument (3). I conclude about arguments (2) and (3) that Leroy Walters was right when he claimed that:

> The proposal to patent non-human animals should be viewed in the context of other ways in which we relate to the animal kingdom... When compared with the ethical issues involved in our breeding, buying, selling, confining, eating, and performing research on animals, the ethical questions surrounding animal patents seem relatively less important... [ibid., pp. 388-9].

What conclusion shall we draw then from our analysis of the arguments offered by the animal rights movement. We should, I believe, conclude that our regulations governing research on animals to minimize suffering should be strengthened to protect farm animals, birds, and rodents used in privately funded research. However, unless we are prepared to radically alter the entire way in which we relate to the animal kingdom, none of the currently articulated arguments offered by this group should lead us to oppose the patenting of transgenic animals.

Section C - The Patenting of Transgenic Animals Viewed from an International Perspective

Several of the opponents of the patenting of transgenic animals have raised concerns that draw upon the observation that American

patenting must be seen in an international perspective. In this section, we will examine the two major concerns arising from this perspective, the argument that patenting of transgenic animals must be wrong because so many countries have explicitly banned the patenting of new types of animals and the argument that patenting will only exacerbate the problem of inequality between the developed countries and the developing countries. Let us look at each of these concerns separately.

Opponents of patenting often make the observation that patents for animals have been granted in only a few countries and that most countries in the developed world actually prohibit animal patents. This is especially true, it is said, of members of the European Patent Convention (EPC). We have already seen that this fact has some moral significance, for it is crucial to undercutting the argument that patenting is required to maintain American competitiveness. Does it have any other moral significance? It would appear not; one doesn't settle moral issues by counting how many countries do or do not allow a particular practice. After all, a practice accepted by many countries even for a long period of time (e.g., slavery) may nevertheless be profoundly immoral while a practice rejected by many countries even for a long period of time (e.g., divorce) may nevertheless be morally acceptable. Still, there is some force to the argument. It at least suggests that we should examine the basis of the widespread legal prohibition on the patenting of animals to see whether those who have banned it have identified powerful arguments for such a ban.

Doing this is not an easy matter. It has been made easier by the appearance of two valuable cross-national surveys [2,3]. What emerges from these surveys is the following: (1) the legal situation is very

unclear in many countries, and some extremely important ones (e.g., Japan and such British Commonwealth countries as Canada and Australia) may - at least in theory - allow for such patents; (2) Article 53 of the European Patent Convention of 1973 explicitly excludes as non-patentable "plant or animal varieties or essentially biological processes for the production of plants or animals, except for microbiological processes or the products thereof." Consequently, the European countries who are participating in that convention are the ones who most clearly oppose the patenting of plants and animals; (3) This is a sharp break from the tradition of the Paris Convention which, from 1883 to 1934, explicitly recognized the patentability of cattle, even if such protection was never actually offered; (4) The best explanation of the shift is that it grew out of the adoption of alternative forms of patent protection for plants under the UPOV convention, and it was adopted without fanfare and without anything other than technical considerations about double-protection motivating it. It is point (4) which makes it clear that there are no moral lessons to be learned from the EPC's banning of the patenting of plants and animals.

Of much greater moral concern is the argument raised by many commentators [5,8] that the patenting of transgenic animals is inappropriate because of its dire economic implications for the third world. Typical of such claims is the following argument offered by Jack Doyle:

> One [issue] is applying high technologies like agricultural biotechnology to countries that might not be able to afford them - or the social and economic consequences they spawn. The genes of high - tech agriculture lodged in every new crop variety or livestock

> breed can carry with them high capital and extensive infrastructure costs... Secondly, there are questions of access. If, for reasons of competitiveness, we begin to hoard scientific advances for commercial and/or political reasons, and only make such discoveries and developments available for a price, that can only breed mistrust and anger and invite charges of technological imperialism from other nations [8, pp.7-8].

The argument in question has both a consequentialist component (patenting and the biotechnology it encourages will lead to bad results for underdeveloped countries) and an equity component (it is unfair for more developed countries to imperialistically exploit less developed countries through biotechnology and its patenting).

There are extraordinarily important but difficult moral and factual issues raised by such claims. In truth, we lack a theory of justice for the international context, one which will enable us to evaluate the moral aspects of the relations between the developed and developing worlds. But we don't need such a fundamental theory to recognize the fallacy committed in the argument: let us grant for now the factual claim that paying both for the patents and for the infrastructure required to use transgenic animals (or plants) would pose great burdens on developing countries, ones they would have difficulty assuming. Let us also grant for now the moral claim that requiring them to assume those costs would be unfair and/or unjust. Why not see helping these countries take advantage of the gains from biotechnology as an obligation to be met by the developed countries through appropriate economic aid, the cost of which is fairly distributed among all

of the citizens of the developed country? Why put the whole burden of that aid on one industry? In other words, the patent office is not the place to structure a morally appropriate program for the international economic order.

Section D - Patenting Transgenic Animals Will Promote Environmentally Unsound Policies

In a time in which people are increasingly sensitive to environmental issues, it is not surprising that much attention has been paid to the environmental impact of the development of transgenic animals encouraged by a system of patenting. In this section, we will examine two very different environmentalist issues which have been raised in connection with patenting.

The first of these issues has been raised by the National Wildlife Federation. It is not opposed either to the development of transgenic animals or even to their release into the wild. It is concerned, however, with the environmental impact of releasing transgenic animals into the wild, and it believes that the encouragement offered by patenting should be withheld at least until better environmental protection laws are passed. To quote from the testimony of Margaret Mellon, the Manager of its Biotechnology Project, on November 5, 1987:

> The current biotechnology framework covers only two narrow categories of animals - invertebrate plant pests and animals used as pesticides. It is wholly inadequate to address the environmental issues raised by engineered animals. Since animals will be engineered, albeit at a slower rate, even in the absence of animal

> patenting, new control programs will be needed regardless of whether the patent law is extended. But in the case that Congress sees fit to extend patent protection to animals, it is imperative that it link that decision to the enactment of new legislation [4, p. 431].

The tone of this presentation of the argument is radically different from the presentation of similar concerns by the Foundation on Economic Trends, which strongly suggests that no system of regulation is likely to be able to do the job [10]. Little argumentation is provided by the Foundation to support that suggestion.

The question of the adequacy of the current regulatory scheme lies beyond the scope of this report, for it can only be resolved after many technical issues raised about the details of the current scheme are clarified. Of particular concern, however, is the apparent reluctance of the EPA to regulate higher forms of life under the Toxic Substances Control Act and of the Fish and Wildlife Service to regulate the use of transgenic animals under its regulatory policies [17]. But the general consequentialist argument that we must be careful to regulate the release of new entities into the environment to protect against unintended and unexpected damage certainly seems sound. Moreover, there seems to be no reason not to apply it here by insisting that any system of patenting must be accompanied by a careful review of the current regulatory scheme and by such revisions as are necessary to make it adequate to cover the release of transgenic animals into the wild. Carrying out such a review and making such revisions would enable us to obtain the consequentialist benefits of a system of patenting without having to pay environmental prices.

A very different argument has been raised by some who have argued - following ideas first developed by Jack Doyle in his book Altered Harvest [6] - that biotechnology developments fostered by a system of patenting may lead to a dangerous decline in the diversity of animal breeds available. Leaving aside for now the question of why such a decline in diversity is viewed as dangerous, it is sufficient for our purposes to note that there is nothing that makes it likely that this will be the resulting trend. In an important article [7], Doyle himself concedes that it is quite possible that increased diversity could be a result of biotechnology. So little more needs to be said about this argument here.

Section E - Patenting Transgenic Animals Will Produce Excessive Burdens on American Agriculture

It is very clear that America's agricultural community is badly divided over the question of the patenting of transgenic animals. The American Farm Bureau Federation strongly supports patenting while the National Farmer's Union and the National Farmer's Organization strongly oppose it. Of special interest is the active opposition of Commissioner of Agriculture Jim Hightower of Texas.

What are the arguments used by the opponents of patenting within the agricultural community and what are their moral, theological, or philosophical dimensions? The most prominent of the arguments seem to be the following: (1) animal patents will result in increased costs to consumers as producers are forced to pay royalties to the owner of animal patents; (2) animal patents will result in an unfortunate concentration in the production of animals as small farmers are forced out by the high costs of the royalties; (3) patent holders will reap

unfair benefits from their royalties as patent holders obtain royalties on the succeeding generations of the patented animals when they reproduce themselves. Let us examine each of these arguments.

Argument (1) has two moral components, an appeal to the unfavorable consequence of consumers having to pay more for their food and an appeal to the injustice of the less affluent (the consumers) transferring more wealth to the more affluent (the large biotech companies). Both of these arguments rest upon the assumption that the costs of production of food will actually increase when patented transgenic animals are used, and it is just this assumption which is challenged by the agricultural community's defenders of patenting. They draw the comparison to the cost implications of more traditional forms of improving the breeding stock. In an important pamphlet, the American Farm Bureau Federation puts the argument as follows:

> Livestock managers are very familiar with animal breeding and, in a rough sort of analogy, breeding fees and higher prices generally paid for genetically superior breeding stock are similar to royalties assessed on patent rights... We expect that the transferred genes will confer increased growth performance, disease resistance, and certain reproductive traits which collectively will lower input costs and produce a more healthful product for the American consumer [9, p.5].

This challenge seems correct, so argument (1) fails because its factual presupposition is probably not true.

Argument (2) raises a very different set of issues. It too argues against patenting by appealing to purported unfavorable

consequences, in this case, greater concentration in the agricultural industry. It too can be and has been challenged on its assumption that patenting will lead to greater concentration. It suffers, however, from the extra problem that it implausibly presupposes both that an increased concentration is bad and that the anti-trust laws cannot be used to protect against excessive concentration. So it seems particularly unpromising.

Argument (3) is a very different matter. It challenges the legitimacy of animal patents on the grounds that self-reproducing animals should not be patented, because that would mean that breeders would unfairly have to pay a fee for each time the patented animal which they purchase reproduces. This argument is one of the main issues raised by Commissioner Hightower [12], and it is why the National Cattlemen's Association supports the patenting of the techniques and processes of producing transgenic animals while opposing the patenting of the actual animals [22]. Three points should be noted. To begin with, it is an open question as to whether patent rights are enforceable over future generations. Secondly, even if they are enforceable, this would probably mean only that the initial royalty fee paid would cover at some extra cost future breeding rights. No system of collecting a fee each time is likely to emerge because of its burdensome nature. Finally, and perhaps most importantly, no justification is ever given for the claim that there is something unfair about patent rights being enforceable over future generations and about the royalty fee covering future breeding rights. There is a long traditional debate over whether there is such a thing as a fair price as distinct from the price set by the market. It would seem that the proponents of argument (3) are presupposing the

legitimacy of some non-market fair price for royalties which they feel is violated when breeders have to pay a royalty fee covering future breeding rights. In light of the notorious difficulties encountered in trying to develop any such notion, this last argument seems unlikely to succeed.

In short, then, those agricultural interests which oppose the patenting of transgenic animals have offered three arguments in opposition, two consequentialist arguments and one which appeals to considerations of justice. The former fail because the assumed consequences probably will not occur; the latter fails because it appeals to an unpromising notion of justice and fairness.

Section F - Summary of Part III

We have examined a large number of arguments which have been offered either against the patenting of transgenic animals or against the process of creating them by genetic engineering which patenting encourages. A number of them fail either because of mistaken factual assumptions or poor logic. Others clearly raise serious issues.

Two of them - the argument about possible damage to the environment and the argument about possible harm to animals - raise consequentialist moral considerations deserving of serious moral attention. Those who have said that these issues should be separated from the appropriateness of patenting have misunderstood the logic of the situation. Patenting of transgenic animals is primarily justified by its beneficial consequences; if these are outweighed by a harmful environmental impact or by inappropriate suffering by animals, patenting should be rejected. Nevertheless, we have argued, we do not need

to reject patenting of transgenic animal on these grounds; we just need to make sure that our environmental impact regulations and our animal protection regulations are adequate to meet the challenge posed by transgenic animals.

Two other arguments raise very different issues. If we are prepared to accept a view that each unique being - including all animals - has an inherent sanctity, or if we are prepared to accept the view that we are charged with the responsibility of being a steward over nature to protect its integrity for its own sake, then we will have far more fundamental problems with engineering transgenic animals or with patenting the resulting animals. Naturally, however, these are some of the least important implications which would have to be drawn if we were to transform our moral thinking by accepting these revolutionary views.

Part IV - Conclusion

We have attempted to summarize and evaluate the main moral, philosophical, and religious arguments for and against the patenting of transgenic animals. We have seen that there are significant consequentialist arguments for allowing such patenting. They are balanced by real consequentialist concerns about the impact upon the environment and upon animals, but these can be met by appropriate regulations. Other arguments that challenge the fundamental legitimacy of patenting are not compelling as currently formulated because they presuppose the acceptance of an entire transformation in our way of thinking about the relation between humanity and animals and/or about the relation between humanity and nature. It remains to be seen

whether those who totally oppose patenting will be able to articulate their reasons for opposition in ways that are more compelling.

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